

WHAT IS CLAIMED IS:

1 1. A method for hemostasis of a puncture site in a blood vessel at an end
2 of a tissue tract, the method comprising:
3 providing a compression member having a proximal end and a distal end and
4 an expansible element disposed at the distal end thereof;
5 inserting the compression member through an opening in a skin surface;
6 positioning a distal end of the expansible element at a predetermined distance
7 away from a wall of the blood vessel; and
8 expanding the expansible element within the tissue tract and against
9 subcutaneous tissue.

1 2. The method of claim 1, wherein the expansible element is only
2 engageable against subcutaneous tissue surrounding the blood vessel wall.

1 3. The method of claim 1, wherein the predetermined distance is in a
2 range from about 0.05 inch to about 0.5 inch .

1 4. The method of claim 3, wherein the predetermined distance is in a
2 range from about 0.2 inch to about 0.3 inch.

1 5. The method of claim 1, wherein the expansible element comprises a
2 balloon.

1 6. The method of claim 5, wherein expanding comprises at least one of
2 axial or radial dilation of the balloon so as to cause compression of the subcutaneous tissue
3 surrounding the blood vessel wall.

1 7. The method of claim 5, wherein expanding comprises inflating a
2 superior aspect of the balloon greater than an inferior aspect of the balloon.

1 8. The method of claim 5, wherein expanding comprises inflating a distal
2 face of the balloon at an angle to the compression member similar to an angle formed
3 between the compression member and the blood vessel.

1 9. The method of claim 5, wherein expanding comprises inflating the
2 balloon to a deployed configuration comprising a conical shape.

- 1 10. The method of claim 5, wherein expanding comprises unfolding
2 concentric folds of the balloon.
- 1 11. The method of claim 5, wherein expanding comprises inflating the
2 balloon to a deployed configuration having a concave distal end.
- 1 12. The method of claim 1, further comprising providing a locating
2 member having a proximal end and a distal end and an expansible member disposed on the
3 distal end thereof.
- 1 13. The method of claim 12, further comprising inserting the locating
2 member through the opening in the skin and in the puncture site prior to or simultaneously
3 with compression member insertion.
- 1 14. The method of claim 13, further comprising deploying the expansible
2 member to an expanded configuration within the blood vessel having a diameter in a range
3 from about 0.05 inch to about 0.5 inch.
- 1 15. The method of claim 14, further comprising locating the puncture site
2 in the blood vessel wall.
- 1 16. The method of claim 15, further comprising providing temporary
2 hemostasis of the puncture site with a plug coupleable to the distal end of the locating
3 member.
- 1 17. The method of claim 16, further comprising contracting and
2 withdrawing the locating member.
- 1 18. The method of claim 1, further comprising imaging the expansible
2 element during positioning.
- 1 19. The method of claim 1, further comprising delivering radio frequency
2 energy, ultrasound energy, or microwave energy to the puncture site.
- 1 20. The method of claim 1, further comprising delivering a clot promoting
2 agent or anti-infection agent to the puncture site.
- 1 21. A kit comprising:

2 a compression member; and
3 instructions to use the compression member for hemostasis of a puncture site
4 in a blood vessel according to claim 1.

1 22. A system for hemostasis of a puncture site in a body lumen, the device
2 comprising:
3 a locating member having a proximal end and a distal end and an expansible
4 member disposed on the distal end thereof; and
5 a compression member at least partially coaxial with the locating member, the
6 compression member having a proximal end and a distal end and an expansible element
7 disposed at the distal end thereof, wherein a distal end of the expansible element is
8 positionable at a predetermined distance away from a wall of the body lumen.

1 23. The system of claim 22, further comprising deployment means
2 coupleable to the proximal end of the locating member so as to move the expansible member
3 between a contracted configuration and an expanded configuration.

1 24. The system of claim 23, wherein the expansible member in the
2 expanded configuration has a diameter in a range from about 0.05 inch to about 0.5 inch.

1 25. The system of claim 24, wherein the expansible member in the
2 expanded configuration has a diameter in a range from about 0.15 inch to about 0.30 inch.

1 26. The system of claim 22, wherein the expansible member comprises
2 stainless steel, shape memory material, or superelastic material.

1 27. The system of claim 22, further comprising a temporary hemostasis
2 member coupleable to the distal end of the locating member.

1 28. The system of claim 27, wherein the expansible element is disposed
2 between the distal end of the compression member and a proximal end of the temporary
3 hemostasis member.

1 29. The system of claim 22, further comprising a deformable membrane at
2 least partially disposed over the expansible member.

1 30. The system of claim 22, wherein the locating member and compression
2 member form an integrated catheter assembly.

1 31. The system of claim 22, wherein the compression member remains
2 proximal a distal end of the expansible member.

1 32. The system of claim 31, further comprising mechanical or visual
2 means on the locating member or compression member.

1 33. The system of claim 31, wherein the predetermined distance is in a
2 range from about 0.05 inch to about 0.5 inch .

1 34. The system of claim 33, wherein the predetermined distance is in a
2 range from about 0.2 inch to about 0.3 inch.

1 35. The system of claim 31, wherein the compression member is fixed
2 relative to the locating member.

1 36. The system of claim 31, wherein the compression member is moveable
2 relative to the locating member.

1 37. The system of claim 22, wherein the locating member is laterally offset
2 from an axis of the compression member.

1 38. The system of claim 22, wherein the expansible element comprises a
2 balloon.

1 39. The system of claim 38, wherein the balloon comprises one or more
2 materials selected from the group consisting of polyethylene, polyethylene terephthalate,
3 polytetrafluoroethylene, nylon, polyurethane, silicone, latex, polyvinyl chloride, and
4 thermoplastic elastomer.

1 40. The system of claim 38, wherein the balloon is pre-formed or pre-
2 molded symmetrically or asymmetrically.

1 41. The system of claim 38, wherein the balloon has a deployed
2 configuration comprising a conical shape.

- 1 42. The system of claim 38, wherein the balloon comprises a plurality of
2 concentric folds that are unfolded in a deployed configuration.
- 1 43. The system of claim 38, wherein the balloon has a deployed
2 configuration comprising a concave distal end.
- 1 44. The system of claim 38, wherein the balloon further comprises a radio-
2 opaque material.
- 1 45. The system of claim 38, further comprising a coating on an outer
2 surface of the balloon.
- 1 46. The system of claim 45, wherein the coating comprises electrically
2 conductive material for the delivery of energy.
- 1 47. The system of claim 46, wherein the energy comprises radio frequency
2 energy or microwave energy.
- 3 48. The system of claim 45, wherein the coating comprises a clot
4 promoting or anti-infection agent.
- 1 49. The system of claim 38, wherein the balloon comprises a semi-
2 permeable membrane.
- 1 50. The system of claim 38, further comprising an inflation assembly
2 coupleable to the proximal end of the compression member and in communication with the
3 balloon.
- 1 51. The system of claim 50, wherein the inflation assembly comprises a
2 source of at least air, fluid, clot promoting agent, anti-infection agent, or radio-opaque
3 medium.
- 1 52. A device for hemostasis of a puncture site in a body lumen, the device
2 comprising:
3 a first tubular member having a proximal end and a distal end;

4 a second tubular member having a proximal end and a distal end and at least
5 partially coaxial with the first tubular member so as to define an inflation lumen
6 therebetween;

7 a balloon disposed at the distal ends of the first and second tubular members
8 and in communication with the inflation lumen, wherein a distal end of the balloon is
9 positionable behind a locator and at a predetermined distance away from a wall of the body
10 lumen.

1 53. The device of claim 52, wherein the predetermined distance is in a
2 range from about 0.05 inch to about 0.5 inch.

1 54. The device of claim 53, wherein the predetermined distance is in a
2 range from about 0.2 inch to about 0.3 inch.

1 55. The device of claim 52, wherein the balloon comprises one or more
2 materials selected from the group consisting of polyethylene, polyethylene terephthalate,
3 polytetrafluoroethylene, nylon, polyurethane, silicone, latex, polyvinyl chloride, and
4 thermoplastic elastomer.

1 56. The device of claim 52, wherein the balloon is pre-formed or pre-
2 molded symmetrically or asymmetrically.

1 57. The device of claim 52, wherein the balloon has an expanded
2 configuration comprising a conical shape.

1 58. The device of claim 52, wherein the balloon comprises a plurality of
2 concentric folds that are unfolded in an expanded configuration.

1 59. The device of claim 52, wherein the balloon has an expanded
2 configuration comprising a concave distal end.

1 60. The device of claim 52, wherein the balloon further comprises a radio-
2 opaque material.

1 61. The device of claim 52, further comprising a coating on an outer
2 surface of the balloon.

1 62. The device of claim 61, wherein the coating comprises electrically
2 conductive material for the delivery of energy.

1 63. The device of claim 62, wherein the energy comprises radio frequency
2 energy or microwave energy.

1 64. The device of claim 61, wherein the coating comprises a clot
2 promoting or anti-infection agent.

1 65. The device of claim 52, wherein the balloon comprises a semi-
2 permeable membrane.

1 66. The device of claim 52, wherein the balloon comprises an expansible
2 member and a deformable membrane at least partially disposed over the expansible member.

1 67. The device of claim 52, wherein the balloon is inflatable with air, fluid,
2 clot promoting agent, anti-infection agent, radio-opaque medium or a combination thereof.